K031678

AUG 2 6 2003

## 510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the SMDA of 1990.

| | |
|---|---|
| 1. Submitter's Name: | Guidant Corporation<br>Vascular Intervention |
| 2. Submitter's Address: | 26531 Ynez Road |
| 3. Telephone: | (909) 914-2676 |
| 4. Fax: | (909) 914-0339 |
| 5. Contact Person: | Bruce Cerwin |
| 6. Date Prepared: | May 28, 2003 |
| 7. Device Trade Name: | HI-TORQUE BALANCE UNIVERSAL™ Guide Wires with Hydrocoat Hydrophilic Coating |
| 8. Device Common Name: | Guide Wire |
| 9. Device Classification Name: | Catheter Guide Wire (74DQX) |
| 10. Predicate Device: | HI-TORQUE BALANCE MIDDLEWEIGHT (BMW) UNIVERSAL™ Guide Wire with Hydrocoat Hydrophilic Coating (K013833) |

11. Device Description:

The HI-TORQUE BALANCE UNIVERSAL™ Guide Wire is a steerable guide wire available in a maximum diameter of 0.0137" and in lengths of 175 cm, 190 cm and 300 cm. The distal segment of the guide wire, up to the hypotube, is coated with hydrocoat to reduce friction for improved guide wire movement within the catheter. The distal tip is offered in a straight shapeable configuration and a pre-shaped "J" configuration. The proximal core has a maximum diameter of 0.0137". The proximal end of the guide wire is coated with PTFE, which reduces friction of the wire within a catheter. The Balance Universal™ Guide Wire is DOC® extendable in the 175 cm and 190 cm lengths.

12. Intended Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of compatible stent devices during therapeutic intravascular procedures.

13. Technological Characteristics:

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

14. Performance Data:

*In vitro* bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE UNIVERSAL™ Guide Wire met the acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and therefore, the HI-TORQUE BALANCE UNIVERSAL™ Guide Wire may be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2003

Guidant Corporation
c/o Mr. Bruce Cerwin
Regulatory Affairs Associate
26531 Ynez Road
Temecula, CA 92591-4628

Re: K031678
HI-TORQUE Balance Universal™ Guide Wire with Hydrocoat Hydrophilic Coating
Regulation Number: 870.1330
Regulation Name: Catheter Guide Wire Introducer
Regulatory Class: Class II
Product Code: DQX
Dated: July 1, 2003
Received: July 3, 2003

Dear Mr. Cerwin:

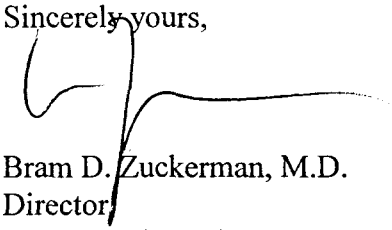
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

## INDICATION FOR USE STATEMENT

**510(k) Number (if known):** K031678

**Device Names:** HI-TORQUE BALANCE UNIVERSAL™ Guide Wire with Hydrocoat Hydrophilic Coating

**Indications for Use:** To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA), percutaneous transluminal angioplasty (PTA) and compatible stent devices during therapeutic intravascular procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031678

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109) (Optional Format 1-1-96)